A Randomized, Multicenter Phase 3 Study to Compare the Efficacy of Panitumumab in Combination with Chemotherapy to the Efficacy of Chemotherapy Alone in Patients with Previously Treated Metastatic Colorectal Cancer

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The primary objective is to evaluate the treatment effect of P*mAb plus FOLFIRI on overall survival (OS) and progression-free survival (PFS) compared to FOLFIRI alone as second line therapy for metastatic colorectal cancer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON29791

Source
ToetsingOnline

Brief title
Eff P'mab+chemo versus chemo in treated metastatic colorectal cancer

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym

metastatic colorectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Amgen
Source(s) of monetary or material Support: Amgen

Intervention

Keyword: chemotherapy, colorectal cancer, Panitumumab

Outcome measures

Primary outcome

Efficacy: Overall survival (OS) and progression free survival (PFS)

Secondary outcome

Efficacy: overall objective response rate (ORR), time to progression (TTP),

duration of response (DOR)

Safety: Incidence of AE*s and significant laboratory changes

Study description

Background summary

Panitumumab is a high affinity fully human IgG2 mAb directed against human EGFr. P*mAb blocks the ligands EGF and TGFα binding to EGFr, inhibits tumor growth, and elicits both tumor regression and eradication of established tumors in murine xenograft tumor models. 1700 Subjects with cancer have been enrolled in P*mAb phase 1,2 and 3 studies. P*mAb has been studied as monotherapy in multiple studies of mCRC and solid tumors. P*mAb has also been studied in combination with chemotherapy for non-small cell lung cancer and with chemotherapy and bevacizumab for mCRC.

Study objective

The primary objective is to evaluate the treatment effect of P*mAb plus FOLFIRI on overall survival (OS) and progression-free survival (PFS) compared

to FOLFIRI alone as second line therapy for metastatic colorectal cancer.

Study design

This is an open label, randomized, multicenter study. Eligible subjects will be randomized in a 1:1 ratio to second line therapy consisting of either P*mAb plus FOLFIRI or FOLFIRI alone. Sample size is 1100 subjects (approximately 550 per treatment arm). P*mAb and chemotherapy will be administered in cycles lasting 14 days, or longer in the event that a cycle is delayed due to toxicity. Subjects will be permitted to receive P*mAb and/or chemotherapy until disease progression or unacceptable toxicities. Subjects with evidence of disease progression will be discontinued from treatment dosing and will be followed for safety and survival

Intervention

Subjects will be randomized to receive P*mAb plus FOLFIRI or FOLFIRI alone. Panitumumab will be supplied at a concentration of 20 mg/ml in 10mL vials. The product will be diluted in a minimum volume of 100mL pyrogen-free 0.9% sodium chloride solution, USP/PhEur (saline solution) and infused by an infusion pump using an in-line filter (0.22 micron) set up.

Study burden and risks

Upon meeting all eligibility criteria and completing all screening assessments, subjects will be randomized into one of the two treatment arms. The following procedures will be performed per the schedule outlined in Appendix A, (page 91-93 of the protocol): medical and medication history, physical exam, vital signs, ECG, patient reported outcomes, hematology lab, chemistry lab, immunogenicity testing, serum testing for CEA, biomarker lab, biomarker and pharmacogenetic analysis on tumor tissues, CT/MRI scans. Adverse events, and concomitant medications will be recorded throughout study participation.

Mild to moderate skin rash is a very common side effect in patients treated with Panitumumab. Other very common adverse events include; nausea, loss of appetite, abdominal pain, constipation, irritation of the mouth, feeling tired, difficulty sleeping, diarrhea and vomiting, dizziness, muscle aching, joint pain, back pain, headache, anxiety and fever. During or within a day or two following the administration of panitumumab, patients may experience infusion reactions. There is also a possibility patient*s immune system may develop antibodies against panitumumab.
All possible adverse effects of receiving panitumumab together with FOLFIRI chemotherapy are still unknown at this time. Patient*s may experience low white blood cell counts, low red blood cell counts, low platelet counts, mouth sores or bleeding gums, increased nausea, vomiting, loss of appetite, weight loss,

diarrhea or tiredness.

Contacts

Public
Amgen

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Scientific
Amgen

Minervum 7061
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Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with adenocarcinoma of the colon or rectum, who are presenting with metastatic disease.
Received one and only one prior chemotherapy regimen consisting of fluoropyrimidine-based chemotherapy.
At least one uni-dimensionallly measurable lesion of at least 20 mm per modified RECIST criteria.

Exclusion criteria

History or known presence of central nervous system metastases
History of another primary cancer (exceptions see page 32)
Prior irinotecan therapy
Prior anti-EGFr antibody therapy or treatment with small molecule EGFr inhibitors.
Systemic chemotherapy, hormonal therapy, immunotherapy or experimental or approved proteins/antibodies < or = 30 days before randomization
Unresolved toxicities from prior systemic therapy that, in the opinion of the investigator, does not qualify the patient for randomization.
Radiotherapy < or = 14 days prior to randomization
Active infection requiring systemic treatment or any uncontrolled infection < or = 14 days prior to randomization
Any investigational agent or therapy < or = 30 days before randomization

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2006
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	N.v.t.

Generic name:	Panitumumab

Ethics review

Approved WMO Date:	04-07-2006
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-11-2006
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-12-2006
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-03-2007
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-06-2007
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-07-2007
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-08-2007
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-10-2007
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO Date:	19-08-2008
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-11-2008
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-01-2009
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-03-2009
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-01-2010
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-12-2010
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2005-004676-20-NL
CCMO	NL13032.091.06